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# When Congress Practices Medicine: How Congressional Legislation of Medical Judgment May Infringe a Fundamental Right

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*Shannon L. Pedersen*[*]

*Current judicial practice gives a great deal of deference to federal legislation in the absence of a possible infringement of a fundamental right. However, legislation that broadly restricts the availability of a medically-accepted treatment based on non-medical grounds, such as the legislation upheld in the 2007 United States Supreme Court decision* Gonzales v. Carhart, *poses a threat to the health and well-being of individual citizens. A proposed flat ban on therapeutic cloning is an example of how this sort of medical legislation can even risk a patient's health well into the future by restricting later access to undeveloped technologies. Although the Supreme Court has recognized some fundamental rights in the area of medicine, it has not yet recognized a right for a patient to submit to safe and effective treatments to preserve her life or health on the recommendation of her physician's reasonable medical judgment. This Comment submits that both the "life" and "liberty" guaranteed in the Due Process Clause encompass this right. I propose that this right can meet the test outlined in* Washington v. Glucksberg, *but it is further grounded in a textual foundation that can escape the uncertainty of a* Glucksberg *analysis altogether. As a result, courts should not uphold such legislation unless Congress demonstrates a compelling government interest and the legislation is narrowly tailored to meet that interest. Congressional legislation that seeks to substitute its judgment for the physician's by banning medically and scientifically-accepted modalities, or modalities that may prove safe and effective in the future such as therapeutic cloning, on a basis unrelated to safety or efficacy infringes this right.*

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## INTRODUCTION

Imagine a future where scientists in the United Kingdom have developed successful therapies for serious diseases using stem cell lines cloned from individual patients.[1] Thorough clinical trials have proven that these treatments are safe and effective, and thousands of patients in the United Kingdom have obtained successful treatments. Physicians and scientists in the United States consider the therapies medically acceptable based on this clinical information. Yet, it is illegal for a United States citizen to obtain such treatment because Congress passed a comprehensive ban on human cloning that included a ban on therapeutic cloning. Does a patient in the United States whose life or health is at stake have any constitutional challenge against this ban?

Although non-cloned stem cell therapy science is undeveloped,[2] the above scenario is not unlikely. Since the mid-1800s, advances in medical science have transformed the practice of medicine.[3] Rather than often acting as an agent to degrade a patient's

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[1] *See* John A. Robertson, *Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate*, 2006 U. CHI. LEGAL F. 1, 3, 4.

[2] *Id.* at 4.

[3] *See, e.g.*, Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 209-10 (1999).

health, medicine can now effect dramatic cures.[4] It is likely that today's discoveries will change the practice of medicine even more in the coming decades.[5] As new therapies become available, patients will surely choose to utilize these treatments when appropriate to preserve life and health. But what options might a patient in the United States have if Congress legislates to ban specific safe and effective modalities on moral or political grounds?

In *Gonzales v. Carhart*,[6] the Supreme Court upheld congressional legislation that criminalized a specific medical technique.[7] Congress enacted the Partial-Birth Abortion Ban Act of 2003[8] after making dubious "findings of fact" that the procedure was "never medically necessary."[9] The Court admitted that some of Congress' findings were erroneous[10] and that evidence indicated the procedure was sometimes the safest option for certain patients.[11] Nevertheless, the Court deferred to the congressional findings to hold the ban constitutional even without a health exception,[12] unlike a similar, previously decided case.[13] The Court indicated that "the State has a significant role to play in regulating the medical

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[4] *Id.*

[5] *See* Marla Vacek Broadfoot, *The Next Big Ideas*, DUKE UNIV. OFFICE OF NEWS & COMMC'NS, Aug. 29, 2006, http://www.dukenews.duke.edu/2006/08/bigidea.html.

[6] 127 S. Ct. 1610 (2007).

[7] *Id.* at 1619.

[8] Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201 (codified as amended at 18 U.S.C. § 1531 (2000 & Supp. IV 2004)).

[9] *Gonzales*, 127 S. Ct. at 1635-38.

[10] *Id.* at 1637-38.

[11] *Id.* at 1635.

[12] *Id.* at 1637.

[13] Stenberg v. Carhart, 530 U.S. 914, 930 (2000) (holding that a state law banning a specific abortion procedure was unconstitutional for lacking a health exception).

profession"[14] and the legislation was reasonable because safe alternative modalities for abortions were available.[15]

However, the Court failed to recognize that Congress fundamentally lacks the context and capacity to "weigh medical evidence adequately."[16] Regardless of Congress' fact-finding power, it simply "is not the appropriate forum for making complex medical decisions."[17] Congress frequently makes legislative decisions on emotional and opportunistic bases rather than on a careful consideration of evidence.[18] Congress may also legislate on moral or repugnance grounds.[19] Although both state and federal regulatory agencies "limit[] medicine's purposes in many ways,"[20] Congress should not direct "choices among procedures that are generally accepted in medical practice."[21] Instead, individual patients, guided by their physicians, should make the decision to submit to a safe and effective treatment.[22]

The effect of this recent effort by Congress to interfere with a patient's treatment extends beyond abortion.[23] Continued judicial deference to Congress on the question of medical appropriateness

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[14] *Gonzales*, 127 S. Ct. at 1633.

[15] *Id.* at 1638.

[16] Jerome P. Kassirer, *Practicing Medicine Without a License—The New Intrusions by Congress*, 336 NEW ENG. J. MED. 1747, 1747 (1997).

[17] *Id.*

[18] *Id.*

[19] *See Gonzales*, 127 S. Ct. at 1633.

[20] M. Gregg Bloche, *The Supreme Court and the Purposes of Medicine*, 354 NEW ENG. J. MED. 993, 993 (2006).

[21] Jeffrey M. Drazen, *Inserting Government between Patient and Physician*, 350 NEW ENG. J. MED. 178, 178 (2004).

[22] *Id.*

[23] George J. Annas, *The Supreme Court and Abortion Rights*, 356 NEW ENG. J. MED. 2201, 2206 (2007).

will only increase public authority over the purposes of all medical practices.[24] It has been said that abortion laws receive heightened judicial scrutiny not because medicine is involved, but because such laws infringe the right of "free reproductive self-determination or autonomy."[25] However, politically-motivated congressional legislation that seeks to substitute its judgment for the physician's by banning a medically-accepted modality infringes rights of autonomy. A flat ban on therapeutic cloning not based on whether the modality is safe and effective is an example of such legislation. "[C]onsidering the matter in light of the Constitution's guarantees of fundamental individual liberty,"[26] as well as the Constitution's textual protection of life,[27] the Court should apply substantive due process principles and invalidate a ban on therapeutic cloning unless Congress demonstrates a compelling government interest and the legislation is narrowly tailored to meet that interest.

This Comment will discuss whether a patient has a constitutional right to submit to a safe and effective medical treatment to preserve his life or health as recommended by his physician's reasonable medical judgment.[28] Part II provides information about therapeutic cloning[29] and the background of current medical regulation at the state and federal levels.[30] This Part

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[24] *See* Bloche, *supra* note 20, at 995.

[25] N.Y. State Ophthalmological Soc'y v. Bowen, 854 F.2d 1379, 1389 (D.C. Cir. 1988).

[26] *Stenberg*, 530 U.S. at 921.

[27] *See* U.S. CONST. amend. V ("No person shall . . . be deprived of life . . . without due process of law . . . .").

[28] *See infra* Parts II-V.

[29] *See infra* Part II.A.

[30] *See infra* Part II.B.

also details how courts review challenges to federal regulations,[31] how courts find "new" fundamental rights,[32] and two specific cases addressing these issues.[33] Part III indicates that the problem lies with inappropriate congressional legislation and the current level of judicial scrutiny.[34] Furthermore, a continuation of this pattern by sustaining a ban on therapeutic cloning violates both life and liberty interests.[35] Part IV evaluates how courts might find a fundamental right for access to safe and effective treatments within the Due Process Clause.[36] This Part will also assess the practicality of applying strict scrutiny analysis to existing medical regulations.[37] Finally, this Comment will recommend that the Court recognize this right to medically-accepted treatment as fundamental and apply strict scrutiny to any law that threatens the right, including a flat ban on therapeutic cloning.[38]

## I. MEDICAL REGULATIONS AND FUNDAMENTAL RIGHTS

### A. What is Therapeutic Cloning?

Embryonic stem cells ("ESCs") are cells present in early-stage embryos that have the potential to differentiate into any type of human tissue.[39] Some ESC research explores whether doctors could

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[31] *See infra* Part II.C.
[32] *See infra* Part II.D.
[33] *See infra* Part II.E.
[34] *See infra* Part III.
[35] *See id.*
[36] *See infra* Parts IV.A-B.
[37] *See infra* Part IV.C.
[38] *See infra* Part V.
[39] *See* Russell Korobkin, *Stem Cell Research and the Cloning Wars*, 18 STAN. L & POL'Y

use these differentiated ESCs to directly treat diseased or dead tissue in a patient.[40] However, a known problem with using ESCs to treat a patient directly is that the patient's immune system may reject the transplanted cells.[41] Although recent research with adult somatic (non-gamete) cells may solve this problem, the technology's infancy and reliance on viral vectors requires further research.[42] The other option for avoiding most deleterious immune responses is therapeutic cloning.[43]

Therapeutic cloning is the common name for therapies derived from somatic cell nuclear transfer.[44] This process involves removing the nucleus from an egg cell and replacing it with the nucleus from a somatic cell.[45] The resulting egg is then a near genetic match to the somatic cell donor.[46] If a scientist stimulates the egg to act as a new embryo to produce ESCs, the donor patient's immune system should not reject the resultant tissue cells.[47] Presently, this technology is not yet available.[48] However, scientists may eventually develop the technology with continued research in the field.[49] If so, therapeutic cloning could provide a safe means to effectively preserve a patient's life or health without "relying on . . .

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REV. 161, 163 (2007).

[40] *Id.* at 164.

[41] *Id.* at 164-65.

[42] *See Skin transformed into stem cells*, BBC NEWS, Nov. 20, 2007, http://news.bbc.co.uk/2/hi/health/7101834.stm.

[43] *See* Korobkin, *supra* note 39, at 165.

[44] *See id.* at 168.

[45] *Id.* at 165.

[46] *Id.*

[47] *Id.* at 165-66.

[48] Korobkin, *supra* note 39, at 166.

[49] *Id.*

external force[s] that fight[]," rather than "harness the body's natural healing powers."[50]

### B. Existing Federal Medical Regulations in the United States

The government can properly regulate trades that "closely concern the public health."[51] For example, the government regulates licensing and the business of medicine as well as "the sale of drugs and devices."[52] Furthermore, since medical information is abundant, "open discussion[s] of medical issues" amongst interested parties, including the government, "promises to improve medical care."[53] As a result, substantial regulations relating to physicians, drugs, and devices appear at both the state and federal level.[54]

The regulation of professions has been considered a state activity since the early years of the United States.[55] In particular, states have a broad ability to "regulate the practice of medicine" through use of their general police power.[56] This power allows the states to adopt laws that are not prohibited by the Constitution.[57] States recognized their ability to use this power for public health disease control as early as the late 1700s,[58] but it was not until after the Civil War that "states began to license physicians and . . .

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[50] *Id.* at 164.
[51] Watson v. Maryland, 218 U.S. 173, 176 (1910).
[52] Drazen, *supra* note 21, at 178.
[53] Kassirer, *supra* note 16, at 1747.
[54] *See id.*
[55] Richards, *supra* note 3, at 202.
[56] *Id.* at 201.
[57] ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 234 (3d ed. Aspen Publishers 2006).
[58] Richards, *supra* note 3, at 204-06.

regulat[e] . . . the practice of medicine."[59] Today, state regulation of medicine continues to include the areas of licensure and discipline of medical professionals.[60]

### 1. *Federal Legislation*

Congress can enact legislation affecting the practice of medicine pursuant to the powers vested in it by the Constitution.[61] For example, Congress enacted the Federal Food, Drug, and Cosmetic Act through its Commerce Clause power.[62] Within such statutes, Congress may grant authority to federal administrative agencies to develop more specific rules.[63] Congress can also pass legislation that affects the practice of medicine in a more direct fashion. One example of this sort of legislation is the Controlled Substances Act,[64] where Congress listed the specific drugs to appear on the initial schedule for control.[65]

In recent years, Congress has attempted to exert more control on the practice of medicine through federal legislation. Some of these attempts have directly affected the choices available to patients.

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[59] *Id.* at 208.

[60] *See id.* at 210. This Comment will not directly address the abundance of state legislation and regulation regarding the practice of medicine. However, this Comment's solution would affect state regulation of medicine because a state cannot legislate in violation of a fundamental right.

[61] *See, e.g.*, McCulloch v. Maryland, 17 U.S. (4 Wheat) 316 (1819).

[62] Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C. (2000)); *See* 21 U.S.C. §331(a) (2000) (prohibiting the introduction of adulterated products into interstate commerce).

[63] *See* discussion *infra* Part II.B.2.

[64] Controlled Substances Act of 1970, Pub. L. 91-513, 84 Stat. 1242 (codified as amended at 21 U.S.C. §§ 801-904 (2000 & Supp. IV 2004)).

[65] 21 U.S.C. § 812 (2000). However, this schedule is updated on an annual basis at the agency level. *Id.* § 812.

For example, in 2005 Congress passed emergency legislation applying only to a single person in an attempt to direct her medical treatment.[66] Congress' bill banning a single abortion practice, upheld in *Gonzales v. Carhart*, is yet another example of Congress' efforts to establish greater authority over the practice of medicine.[67] Members of Congress have also repeatedly tried to pass legislation to ban both reproductive and therapeutic cloning,[68] though as of this date such attempts have been unsuccessful.[69] However, the proposed flat ban on therapeutic cloning makes no distinction based on whether the treatment is deemed safe and effective.[70]

### 2. *Federal Administrative Rules*

Federal administrative agency regulation of medical practice is common.[71] The U.S. Department of Health and Human Services ("HHS") is the "principal agency for protecting the health of all Americans."[72] Two HHS agencies responsible for many federal regulations affecting the practice of medicine are the Centers for

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[66] Relief of the Parents of Theresa Marie Schiavo, Pub. L. No. 109-3, 119 Stat. 15 (2005). The legislation gave Ms. Schiavo's parents standing to sue in federal court for the purposes of de novo review of a constitutional claim regarding the removal of Ms. Shiavo's nutritional support. *Id.* However, Congress' attempt to direct treatment ultimately failed because upon review, the federal district court denied the parents' request for a temporary restraining order. *See* Schiavo *ex rel.* Schindler v. Schiavo, 357 F. Supp. 2d 1378, 1388 (M.D. Fla. 2005).

[67] *See infra* Part II.E.2.

[68] KERRY LYNN MACINTOSH, ILLEGAL BEINGS 76-78 (2005).

[69] *See, e.g.*, H.R. 2564, 110th Cong. (2007); H.R. 1357, 109th Cong. (2005); H.R. 534, 108th Cong. (2003); H.R. 2505, 107th Cong. (2001).

[70] *See* Steven Goldberg, *Cloning Matters: How* Lawrence v. Texas *Protects Therapeutic Research*, 4 YALE J. HEALTH POL'Y L. & ETHICS 305, 308 (2004).

[71] *See* Kassirer, *supra* note 16, at 1747.

[72] HHS.gov, HHS: What We Do, http://www.hhs.gov/about/whatwedo.html (last visited Aug. 11, 2008).

Medicare and Medicaid Services ("CMS") and the Food and Drug Administration ("FDA").[73] CMS promotes quality care for beneficiaries of its programs.[74] Meanwhile, the FDA is responsible for ensuring the safety and efficacy of drugs, biologics, and medical devices.[75]

Federal agencies regulating medicine do so based on a congressional delegation of statutory authority.[76] When Congress passes complex legislation such as the Federal Food, Drug, and Cosmetic Act,[77] it delegates authority to an agency to create rules necessary to carry out the requirements of the statute.[78] Although there are many options for creating administrative rules,[79] it is common for agencies to conduct "notice and comment" rulemaking.[80] This type of rulemaking requires that the agency give public notice of the proposed rule and allow interested parties to submit comments.[81] The agency must consider these comments when creating the final

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[73] *Id.*

[74] HHS.gov, CMS, Mission, Vision, Goals, http://www.cms.hhs.gov/MissionVisionGoals/ (last visited Aug. 11, 2008).

[75] FDA.gov, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Aug. 11, 2008).

[76] *See* Am. Power & Light Co. v. S.E.C., 329 U.S. 90, 105 (1946) ("[I]t then becomes constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority.").

[77] Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2000 & Supp. IV 2004)); *see also* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 103 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.A. § 247d-5a (West 2007)).

[78] *See* United States v. Mead Corp., 533 U.S. 218, 227 (2001) ("Delegation of such authority may be shown in a variety of ways, as by an agency's power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.").

[79] *See generally* Administrative Procedure Act, 5 U.S.C. §§ 551-559 (2006) (providing procedures for agency rulemaking and adjudication).

[80] 5 U.S.C.A. § 553 (West 2007).

[81] 5 U.S.C.A. § 553.

rule.[82] However, the agency does not have to adopt any comment proposal and is limited in its ability to incorporate specific comments in the final rule.[83] In addition, agencies make determinations based on their existing rules that may have an effect on the practice of medicine.[84] For example, the FDA approves New Drug Applications ("NDAs") based on the procedures and requirements the agency adopted through rulemaking.[85]

### C. Judicial Review of Medical Regulations

#### *1. Standard of Review*

Regulations affecting health are often controversial.[86] As a result, regulations involving controversial practices, albeit medically-accepted, are often disputed in the courts.[87] Challenges to medical regulations fail or succeed based on the level of review the reviewing court applies. As with other laws, the applicable standard of review depends on whether or not there is a fundamental right involved.[88] If the reviewing court finds a fundamental right, then the court will apply strict scrutiny to the law.[89] On the other hand, if no fundamental right is involved, the court will only apply a rational

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[82] 5 U.S.C.A. § 553.

[83] Chocolate Mfrs. Ass'n of U.S. v. Block, 755 F.2d 1098, 1104 (4th Cir. 1985) ("An agency . . . does not have carte blanche to establish a rule contrary to its original proposal simply because it receives suggestions to alter it . . . .").

[84] *See* 5 U.S.C.A. §§ 554, 555, 558 (West 2007).

[85] *See generally* 21 C.F.R. § 310 (2008) (pertaining to new drug approval processes).

[86] Robert Steinbrook, *Peer Review and Federal Regulations*, 350 NEW ENG. J. MED. 103, 103 (2004).

[87] *See* Bloche, *supra* note 20, at 993.

[88] Williams v. Pryor, 240 F.3d 944, 947 (11th Cir. 2001).

[89] *Id.*

basis review.[90] Therefore, requiring that the court find a fundamental interest before selecting the standard of review allows courts to avoid balancing competing interests every time.[91] The requirements for these two standards of review vary, as do their results.[92]

When the government infringes upon a fundamental right, courts apply a stringent standard.[93] Strict scrutiny requires the government to first justify that the law serves a "compelling government interest."[94] If the state proves such an interest exists, then it must also demonstrate that the law was "narrowly drawn" to address only those compelling interests.[95] Although strict scrutiny is not always "fatal in fact,"[96] courts do find most laws unconstitutional under this standard.[97] Rarely, the Supreme Court has applied strict scrutiny to cases involving medical treatment decisions.[98]

Conversely, when a court finds that legislation does not involve a fundamental interest, it will only conduct a rational basis review.[99] This standard requires that the court determine whether the legislature's means are rationally related to a legitimate government interest.[100] Unlike strict scrutiny, the government does not have to show why its law meets this standard. Instead, the burden is on the

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[90] *Id.* at 948.

[91] Washington v. Glucksberg, 521 U.S. 702, 722 (1997).

[92] *See Williams*, 240 F.3d at 948.

[93] *Id.*

[94] *Id.* at 947.

[95] *Id.* 948.

[96] Adarand Constructors, Inc. v. Pena, 515 U.S. 200, 237 (1995) (quoting Fullilove v. Klutznick, 448 U.S. 448, 519 (1980) (Marshall, J., concurring in judgment)).

[97] *Williams*, 240 F.3d at 948.

[98] *See infra* text accompanying notes 122-27.

[99] *Williams*, 240 F.3d at 948.

[100] *Id.*

challenger to prove that the law is not rationally-related to such an interest.[101] Furthermore, the interest does not even have to be the one the legislature actually intended when enacting the law.[102] Therefore, if there is "any reasonably conceivable" interest, a court will likely find a law constitutional under rational basis review.[103] As a result, unlike strict scrutiny, courts typically find most laws constitutional when they apply a rational basis review.[104]

### 2. *Judicial Deference to Legislature and Agencies*

When reviewing legislation, courts must ensure that Congress did not attempt to alter the requirements of the Constitution by means of the challenged law.[105] Although the judiciary will grant respect to Congress as a coequal branch of government, courts will not defer to Congress on constitutional questions.[106] However, courts will choose a reasonable alternative interpretation to federal statutes in order to avoid finding them unconstitutional.[107] Courts give substantial deference to Congress' "predictive judgments" but do not insulate them from all review.[108] This deference occurs, in part, because of Congress' ability to perform fact-finding that the judiciary lacks.[109]

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[101] *Id.* (quoting F.C.C. v. Beach Commc'ns, 508 U.S. 307, 313-15 (1993)).

[102] *Id.*

[103] *Id.* (quoting *Beach Commc'ns*, 508 U.S. at 314).

[104] *Williams*, 240 F.3d at 948.

[105] Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is.").

[106] *See* Columbia Broad. Sys. Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 103 (1973).

[107] Gomez v. United States, 490 U.S. 858, 864 (1989).

[108] Turner Broad. Sys., Inc. v. F.C.C., 512 U.S. 622, 665-66 (1994) (finding that legislators often anticipate the impact of future events as part of the policymaking process).

[109] *See* City of Richmond v. J. A. Croson Co., 488 U.S. 469, 500 (1989).

Nonetheless, the Supreme Court has often deferred to the medical community's understanding of its purposes, even in cases where the Court ultimately treated federal law as controlling.[110]

Judicial review of agency decision making is often reviewed with great deference.[111] Generally, as long as the agency has not exceeded its statutory mandate, courts review agency rules and orders using an "arbitrary and capricious" standard.[112] This very deferential standard of review upholds rulemaking unless the agency "relied on factors which Congress has not intended it to consider," did not consider "an important aspect of the problem," explained the decision in a way that "runs counter to the evidence before the agency," or "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[113] In contrast, rules and orders made through a formal hearing are reviewed using a "substantial evidence" standard.[114] The substantial evidence standard is also quite deferential.[115] If an agency action infringes a constitutional right, however, courts will not maintain this deference.[116] Instead, courts will make an independent assessment of the agency's action.[117]

### D. Finding New Fundamental Rights Under the Due

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[110] *See* Bloche, *supra* note 20, at 993-94 (referring to the Supreme Court's citations to amicus briefs from physician organizations, including the American Medical Association in a Fourth Amendment case).

[111] *See* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).

[112] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983).

[113] *Id.* at 43.

[114] See 5 U.S.C.A. § 706(2)(E) (West 2007).

[115] *See* Universal Camera Corp. v. N.L.R.B., 340 U.S. 474, 488 (1951) ("[A] reviewing court is not barred from setting aside a . . . decision when it cannot conscientiously find that the evidence supporting that decision is substantial . . . .").

[116] 5 U.S.C.A. § 706(2)(B) (West 2007).

[117] Porter v. Califano, 592 F.2d 770, 780 (5th Cir. 1979).

**Process Clause**

The Due Process Clause of the Fifth Amendment to the United States Constitution declares that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law."[118] The Supreme Court has articulated that this clause protects an individual from more than unfair governmental process and physical restraint.[119] In this respect, liberty is a "rational continuum" recognizing that "certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment."[120] However, the Court has been reluctant to expand the concept of due process and considers the question of new rights with the utmost care.[121]

The Court has found constitutionally-protected rights when reviewing medical legislation involving contraceptives,[122] abortion,[123] and the right to refuse medical treatment.[124] However, even in these cases, the Court did not always indicate whether there was a "fundamental" right.[125] In addition, the Court has only found an affirmative right to medical treatment when the government denies necessary medical treatment to prisoners.[126] Therefore, convincing the Court to find a new fundamental right is a difficult proposition

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[118] U.S. CONST. amend. V.

[119] *Glucksberg*, 521 U.S. at 719.

[120] Raich v. Gonzales, 500 F.3d 850, 862 (9th Cir. 2007) (quoting Poe v. Ullman, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting)).

[121] *Glucksberg*, 521 U.S. at 720.

[122] *See, e.g.*, Eisenstadt v. Baird, 405 U.S. 438 (1972).

[123] *See, e.g.*, Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992).

[124] *See, e.g.*, Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990).

[125] *See id.* at 278 (holding there was a "constitutionally protected liberty interest" rather than specifically stating there was a fundamental right).

[126] *See, e.g.*, Estelle v. Gamble, 429 U.S. 97 (1976). *See also* CHEMERINSKY, *supra* note 57, at 818-19.

because the Court has not always provided consistent criteria for recognizing fundamental rights.[127]

### 1. Glucksberg's *Two-Prong Test*

In *Washington v. Glucksberg*, the Court articulated a two-prong test for use when reviewing asserted liberty interests.[128] The Court declared that in order to find a new fundamental liberty right, the right must meet two factors.[129] First, history and tradition must support the right.[130] Second, the challenger must carefully describe the asserted right.[131] Courts often address these prongs in reverse, since consideration of whether a right is fundamental depends first on the definition of that right.[132]

The Supreme Court has stated that an asserted fundamental liberty right must include a " 'careful description' of the asserted fundamental liberty interest."[133] The Court will not accept a description it finds too broad and will often perform the substantive due process analysis using a more narrow description of its own creation.[134] For example, in *Cruzan*, the Court did not evaluate whether a person had a "right to die," but instead asked whether a person had a "right to refuse lifesaving hydration and nutrition."[135]

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[127] Cass R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 HASTINGS L.J. 987, 989 (2002).
[128] *Glucksberg*, 521 U.S. at 720-21.
[129] *Id.* at 720.
[130] *Id.* at 720-21.
[131] *Id.* at 721.
[132] *See Raich*, 500 F.3d at 863.
[133] *Glucksberg*, 521 U.S. at 721.
[134] *See id.* at 722.
[135] *Id.* at 722-23 (quoting *Cruzan*, 497 U.S. at 279).

Other cases in recent jurisprudence lend support to the idea that a court's definition of the asserted fundamental right will have a significant impact on the outcome of a case.[136] If a right is described too broadly, it can encompass too much, but if it is described too narrowly, it may appear trivial.[137] It is possible that courts use this prong of the *Glucksberg* test purposely to avoid acknowledging asserted rights.[138]

The Court has also noted that a right is protected as a fundamental liberty interest only when supported by history and tradition.[139] The right must be "deeply rooted in this Nation's history and tradition" and " 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.' "[140] Courts will look to history, state statutes, common law doctrine, and cases on the subject to answer this question.[141] This examination closely depends on the court's previously determined definition of the asserted right.[142] If the court redefines the right in a narrow fashion, it is unlikely the court will go on to find the right is historically protected.[143] In *Glucksberg*, the Supreme Court's definition of the right as one "to commit suicide which itself includes

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[136] *See, e.g.*, *Raich*, 500 F.3d at 864 (adding "the use of marijuana" to Raich's description of the asserted right at issue, which narrowed the definition to such a degree that the court did not find the asserted right to be fundamental).

[137] Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (*Abigail Alliance II*), 495 F.3d 695, 716 (D.C. Cir. 2007) (Rogers, J., dissenting).

[138] *Id.*

[139] *Glucksberg*, 521 U.S. at 720-21.

[140] *Id.* (citations omitted).

[141] *See id.* at 724.

[142] *See supra* text accompanying note 134.

[143] *See, e.g.*, *Raich*, 500 F.3d at 866 (holding there was no fundamental right to use marijuana medicinally).

a right to assistance in doing so"[144] led the Court to conclude that history did not support this right.[145]

### 2. *Alternative Theories for Finding New Rights*

The *Glucksberg* test articulated in the discussion above is not the only method for finding a new fundamental right. Although courts still apply this test,[146] there are alternative theories for finding new fundamental rights under the Due Process Clause. One theory is still based on an interpretation of "liberty," while a second theory has a more concrete textual basis.

In *Lawrence v. Texas*,[147] the Supreme Court acknowledged that "history and tradition" were not the ending point of a substantive due process analysis.[148] *Lawrence* involved a state law that criminalized sodomy between consenting, adult homosexuals, even when done in the privacy of their own home.[149] The Court held the law was unconstitutional because "[t]he liberty protected by the Constitution" allowed homosexuals the choice to express themselves intimately.[150] However, the Court did not explicitly hold there was a fundamental right to homosexual sodomy.[151] Yet, the Court noted that even if history does not indicate an interest as fundamental, "an emerging awareness" of a liberty interest in modern times might

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[144] *Glucksberg*, 521 U.S. at 723.
[145] *Id.* at 728.
[146] *See infra* Part II.E.
[147] 539 U.S. 558 (2003).
[148] *Id.* at 572 (quoting County of Sacramento v. Lewis, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)).
[149] *Id.* at 562-63.
[150] *Id.* at 558.
[151] *Id.* at 586 (Scalia, J., dissenting).

require protection of an asserted right.[152] In particular, the Court explained "the fact that the governing majority . . . has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice."[153]

The decision in *Lawrence* was also based on the already-recognized fundamental privacy interest.[154] In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Court noted that "[a]t the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."[155] A challenger might convince a court to recognize a new fundamental right on similar privacy grounds. However, courts have not yet accepted that medical decisions outside of the procreation and contraception contexts fall within the realm of "personal decisions" constitutionally protected as privacy interests.[156] Meanwhile, courts have continued to use the two-prong test from *Glucksberg* for other medical decisions.[157] For example, the Ninth Circuit Court of Appeals used the *Glucksberg* test in *Raich* to hold that there was no fundamental right to use medical marijuana.[158] The court acknowledged that the *Lawrence* framework might apply in the case, but denied finding a fundamental right since "the use of medical marijuana ha[d] not obtained the degree of recognition today [as]

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[152] *Lawrence*, 539 U.S. at 572. The Court did not apply strict scrutiny to the challenged law, but instead found that the law furthered no legitimate state interest. *Id.* at 578.

[153] *Id.* at 577 (quoting Bowers v. Hardwick, 478 U.S. 186, 216 (1986) (Stevens, J., dissenting)).

[154] *See id.* at 578-79.

[155] *Planned Parenthood*, 505 U.S. at 851.

[156] *See Lawrence*, 539 U.S. at 574.

[157] *See, e.g.*, *Abigail Alliance II*, 495 F.3d at 702-03; *Raich*, 500 F.3d at 862-63.

[158] *Raich*, 500 F.3d. at 866.

private sexual conduct."[159]

In addition to "liberty," the Due Process Clause also explicitly protects "life."[160] All other constitutional rights, including those recognized as fundamental under the due process liberty interest, depend on the ability to stay alive.[161] Therefore, it is arguable that courts should require "[s]tate deprivation of life" to have at least the same justification as required for other fundamental liberty deprivations.[162] A corollary right is the right to *preserve* one's life.[163] This concept is supported by sources from the founding of the United States, establishing the defense of life as a "natural right."[164]

The textual hook for "life" in the Due Process Clause itself is important because of the Court's skepticism when reviewing asserted liberty rights.[165] Unlike the right to privacy that the Court has recognized in some situations, the asserted right to preserve life is not a "second derivative" of liberty.[166] This is an important distinction because the Court's prevailing opinion is to deny protection for an unenumerated right unless it meets the two-part *Glucksberg* test.[167] However, the *Glucksberg* test may be unduly restrictive when a right is expressly stated in the Constitution.[168] Enumerated rights should not trigger concerns about unwarranted judicial expansion of

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159 *Id.*at 865.

160 *See, e.g.*, Robertson, *supra* note 1, at 9.

161 *See id.*

162 *See id.* at 9-10.

163 *Abigail Alliance II*, 495 F.3d at 714 (Rogers, J., dissenting).

164 Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1819 (2007).

165 *See Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).

166 *Id.*

167 *See* Korobkin, *supra* note 39, at 183.

168 *Abigail Alliance II*, 495 F.3d at 716 n.1 (Rogers, J., dissenting).

substantive due process rights.[169]

### E. Judicial Review Results

Federal courts have heard many cases involving challenges to medically-related federal laws and agency regulations. This section will examine two cases in particular that exemplify the current jurisprudence in the area of medical decisions and fundamental rights. The first case pertains to administrative agency regulations while the second is about direct federal legislation. In both cases, the courts involved did not find that government action infringed fundamental rights.

#### 1. *Federal Administrative Law:* Abigail Alliance

In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, an en banc panel from the Court of Appeals for the District of Columbia Circuit declined to hold that a terminally-ill patient had a fundamental right to use experimental drugs that had passed the initial stage of clinical testing.[170] The decision was the result of a rehearing of the case after a three-judge panel found that the right did exist.[171] Assuming the definition of the right was carefully described,[172] the court focused its inquiry on whether the

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[169] *See id.* at 722.

[170] *Id.* at 701.

[171] Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (*Abigail Alliance I*), 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, *Abigail Alliance II*, 495 F.3d 695 (D.C. Cir. 2007). The dissenting judge in this case wrote the majority opinion for the subsequent en banc panel. *Id.* at 697.

[172] The court expressed doubt that it was carefully described since the right depended on a regulatory determination that was subject to change. *Abigail Alliance II*, 495 F.3d at 702, 703 n.6.

purported right was "deeply rooted in this Nation's history, tradition, and practices."[173] The court chose to consider whether there was a historical right of access to drugs not yet deemed safe or effective.[174]

After conducting a historical review, the court determined there was a long history of government regulation of the safety and efficacy risks of drugs.[175] The court admitted that the specific FDA regulations involved were recent,[176] and a lack of historical governmental interference "might be some evidence that a right is deeply rooted."[177] However, the court believed that "the lack of prior governmental regulation of an activity tells us little about whether the activity merits constitutional protection."[178] The court then decided that the Alliance had not provided evidence that weighed the historical question in favor of finding a fundamental right.[179] In particular, the court noted that the drugs the Alliance wanted access to were merely *potentially* life-saving because they had no proven therapeutic effect.[180] The court stated, however, that it would "not address the broader question of whether access to medicine might ever implicate fundamental rights."[181]

Since the court did not find a fundamental right, it applied

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[173] *Id.* at 703.

[174] *Id.* The appellants focused their argument on the theory that there was no history of governmental interference with a doctor's judgment about the efficacy of a drug. *Id.*

[175] *Id.* at 703-06.

[176] *Id.* at 705-06.

[177] *Abigail Alliance II*, 495 F.3d at 706.

[178] *Id.* at 707. The court also expressed concern that finding constitutional rights based only on a lack of historical regulation would undermine the modern administrative state. *Id.*

[179] *Id.* at 711. The court also declined to find a fundamental right based on the appellant's common law arguments of necessity, intentional interference with rescue, and self-defense. *Id.* at 707-09.

[180] *Id.* at 710.

[181] *Id.* at 701.

rational basis review to the regulation.[182] The court held that the government's legitimate interest in protecting patients from unsafe drugs was rationally related to the regulation limiting access to experimental drugs.[183] Furthermore, the court indicated that the legislative branch was more appropriate to balance the interests of medical technology, and that its decisions were entitled to deference.[184]

The dissent[185] vehemently disagreed with the majority's finding.[186] It believed that the majority mistakenly combined the analysis of whether there was a fundamental right with whether the government's regulation would survive strict scrutiny.[187] Instead, the dissent would have first examined if there was a fundamental right "to preserve one's life," and only after finding such a right would it consider whether the government's justification for infringing on that right was constitutional.[188] The dissent pointed out that the FDA's regulatory authority did not extend to physicians, and that the FDA did not prohibit off-label use of regulated drugs.[189] Furthermore, FDA regulations historically addressed restrictions due to misbranding and adulteration concerns rather than efficacy.[190]

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[182] *Abigail Alliance II*, 495 F.3d at 712.

[183] *Id.* at 713.

[184] *Id.*

[185] The same judge who wrote the majority opinion in the original three-panel decision, Judge Griffith, wrote the dissenting opinion. *See Abigail Alliance I*, 445 F.3d at 471.

[186] *Abigail Alliance II*, 495 F.3d at 714 (Rogers, J., dissenting) ("The court's opinion reflects a flawed conception of the right claimed . . . and a stunning misunderstanding of the stakes.").

[187] *Id.*

[188] *Id.* at 716.

[189] *Id.* at 725-26.

[190] *Id.* at 714.

Ultimately, the dissent would have found a fundamental right because there was not a "historical pedigree" of "encumbrances on the treatment decisions of a patient and her physician."[191]

The dissent also believed that common law supported the Alliance's asserted right of medical self-defense.[192] Limitations on the use of common law did not mean the right did not exist, but rather that competing government interests might sometimes support a deprivation of the right.[193] The dissent also noted that this was not a novel argument because the Supreme Court already protected the right of a woman to have an abortion when her life or health was at risk.[194] History showed that a woman's right to have an abortion as medical self-defense was independent from her right to have an abortion as a personal choice.[195] The dissent also expressed frustration that "the right to try to save one's life is left out in the cold despite its textual anchor in the right to life."[196]

### 2. *Congressional Legislation:* Gonzales v. Carhart

#### a. What Prompted Congressional Action?

In 2000, the Supreme Court held in *Stenberg v. Carhart* that a

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[191] *Abigail Alliance II*, 495 F.3d at 726 (Rogers, J., dissenting).

[192] *Id.* at 718-19.

[193] *Id.* at 719.

[194] *Id.* The dissent believed that the holding in *Gonzales v. Carhart*, where the Court did not require an exception for health, was not inapposite because there were other treatment alternatives available in that case as well. *Id.* at 721.

[195] *Id.* at 716-17.

[196] *Abigail Alliance II*, 495 F.3d at 715.

state law banning a particular modality of late-term abortion was unconstitutional because it did not contain a health exception.[197] The Court reiterated that an exception was required "where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." [198] The State of Nebraska argued that the ban would never endanger a woman's health because other safe alternative abortion methods were available.[199] The Court disagreed, determining that the State did not prove that an exception to the ban was never necessary and that there was "substantial medical authority" indicating the ban might endanger the health of some women.[200] However, Justice Kennedy's dissent emphasized that the statute advanced "critical state interests" and did not place an undue burden upon a woman's right to an abortion.[201] Furthermore, he believed that the state had a right to make a moral judgment regarding the procedure.[202]

Congress responded to *Stenberg* by passing the Partial-Birth Abortion Ban Act of 2003 ("Act").[203] President George W. Bush

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[197] *Stenberg*, 530 U.S. at 930. The Court also held that the law created an undue burden on a woman's right to choose an abortion. *Id.*

[198] *Id.* (quoting *Planned Parenthood*, 505 U.S. at 879) (alteration in original).

[199] *Id.* at 931.

[200] *Id.* at 937-38.

[201] *Id.* at 957 (Kennedy, J., dissenting). The state interests Justice Kennedy discusses include an interest in protecting the "life of the unborn" and ensuring the compassion of the medical profession. *Id.* at 961-62.

[202] *Stenberg*, 530 U.S. at 962 (Kennedy, J., dissenting).

[203] Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201 (codified as amended at 18 U.S.C. § 1531 (Supp. IV 2004)). A form of this bill passed both houses of Congress twice in previous years, but was vetoed by President Clinton on both occasions and the Senate was unable to override the vetoes. *See* H.R. 1122, 105th Cong. (1997); H.R. 1833, 104th Cong. (1995).

signed the Act into law on November 5, 2003.[204] It was the first time Congress had ever banned an approved medical procedure.[205] The Act did have an exception for the life of the mother, but still did not contain a health exception.[206] Even so, supporters of the Act believed that courts would find the law constitutional, unlike the Nebraska law at issue in *Stenberg*.[207] The reason for this confidence was that legislators added findings of fact to the bill stating that the banned procedure was never medically necessary.[208] According to the findings, "overwhelming evidence . . . compiled at extensive congressional hearings . . . demonstrates that a partial-birth abortion is never necessary to preserve the health of a woman, poses significant health risks to a woman . . . and is outside the standard of medical care."[209] Not all members of Congress supported these findings and instead introduced evidence into the record showing that a health exception was warranted.[210] Nonetheless, an amendment in the Senate to add a health exception did not pass[211] and the findings

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[204] Annas, *supra* note 23, at 2203.

[205] 149 CONG. REC. S11589-06, S11597 (2003) (statement of Sen. Boxer) ("This is the first time any Congress has ever outlawed a medical procedure that is supported by the medical community.").

[206] 18 U.S.C. § 1531.

[207] *See* 149 CONG. REC. S11589-06, S11591-S11596 (statement of Sen. Santorum) ("[T]here has never been a case introduced that has not been refuted [in so many] different ways that suggests that this procedure is necessary for [the] health [of the mother].").

[208] 149 CONG. REC. S11589-06, S11601 (statement of Sen. Murray) ("The authors of this bill tried to get around the law of the land by inserting a section of congressional findings in their unconstitutional bill.").

[209] Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, § 2(5), 117 Stat. 1201, 1202 (2003).

[210] *See, e.g.*, 149 CONG. REC. S11589-06, S11595 (statement of Sen. Boxer) ("With all due respect to my colleague from Pennsylvania . . . I trust an OB/GYN more than I do him [Senator Santorum] on matters pertaining to a woman's health and her body.").

[211] *See* 149 CONG. REC. S3608-01 (2003).

remained in the bill.[212]

### b. Judicial Review of the Ban

Multiple parties challenged the Act in several federal courts.[213] All of the district courts and courts of appeals hearing the challenges found the Act unconstitutional on either vagueness grounds or due to the lack of a health exception.[214] These courts did not defer to Congress' finding that the banned procedure was never medically necessary.[215] Instead, the district courts evaluated evidence from both sides during trial and found that the procedure was either "sometimes[] the safest abortion procedure,"[216] or that "a significant body of medical opinion" found that the procedure had safety advantages at least "for some women in some circumstances."[217]

The Supreme Court granted certiorari and reversed the decisions of the lower courts.[218] Justice Kennedy's majority opinion tracked his dissent from *Stenberg*.[219] The Court first stated that the government had a "legitimate and substantial interest in preserving and promoting fetal life."[220] After determining that the Act was not

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[212] *See* Partial-Birth Abortion Ban Act, § 2.

[213] *See, e.g.*, Gonzales v. Carhart, 127 S. Ct. 1610, 1619 (2007).

[214] *See* Annas, *supra* note 23, at 2204.

[215] *Gonzales*, 127 S. Ct. at 1636.

[216] *Id.* (quoting Carhart v. Ashcroft, 331 F. Supp. 2d 805, 1017 (D. Neb. 2004)).

[217] *Id.* (quoting Nat'l Abortion Fed'n v. Ashcroft, 330 F. Supp. 2d 436, 480 (S.D.N.Y. 2004)).

[218] *Id.* at 1639.

[219] *See* Annas, *supra* note 23, at 2204. In addition, the composition of the Court was different than it had been for *Stenberg*; Chief Justice Roberts replaced Chief Justice Rehnquist and Justice Alito replaced Justice O'Connor. *Id.* at 2203. The two new justices voted to uphold the law, shifting the previous 5-4 split to a similarly split opposing view. *Id.* at 2204.

[220] *Gonzales*, 127 S. Ct. at 1626.

unconstitutionally vague, overbroad, or facially invalid,[221] the Court decided that the ban did not create a substantial obstacle to previability abortions.[222]

The Court based this decision in large part on the congressional findings of fact accompanying the bill.[223] Although the Court confirmed that it "retain[ed] an independent constitutional duty to review factual findings where constitutional rights are at stake,"[224] it nevertheless deferred to the findings even though some were erroneous.[225] The Court noted that Congress had the competence to balance risks when "the regulation is rational and in pursuit of legitimate ends."[226] The Court therefore accepted that Congress had the power to ban a medically-accepted procedure[227] in the face of medical uncertainty.[228] Furthermore, the Court declared that "[t]he law need not give abortion doctors unfettered choice in the course of their medical practice, nor should it elevate their status above other physicians in the medical community."[229]

Justice Ginsburg wrote a scathing dissent against what she considered to be the majority's "flimsy and transparent justifications"

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[221] *Id.* at 1627.

[222] *Id.* at 1632.

[223] *Id.* at 1632-33. "The Act's purposes are set forth in recitals preceding its operative provisions." *Id.* at 1632.

[224] *Id.* at 1637.

[225] *Gonzales*, 127 S. Ct at 1637-38. The Court provided two examples of erroneous findings of fact: the banned procedure was never taught in medical schools and there was medical consensus that the banned procedure was never medically necessary. *Id.*

[226] *Id.* at 1638.

[227] The fact that the procedure is taught at several major medical schools and is performed at major medical institutions indicates it is within the standard of medically-accepted care. *See* Planned Parenthood Fed'n of Am. v. Ashcroft, 320 F. Supp. 2d 957, 1029 (N.D. Cal. 2004).

[228] *Gonzales*, 127 S. Ct at 1638.

[229] *Id.* at 1636.

for finding the ban constitutional.[230] Her dissenting opinion emphasized that the district courts' findings of fact were based on more extensive medical and scientific evidence from better-qualified witnesses than the congressional findings.[231] As a result, the lower courts rejected Congress' findings as unsupported and unreasonable.[232] Justice Ginsburg agreed with the lower courts' determinations, noting the significant medical authority finding the banned procedure to be the safest method in some instances.[233] She further stated that the Court's decision "deprive[d] women of the right to make an autonomous choice [about different procedures], even at the expense of their safety."[234]

## II. THE PROBLEM: LEGISLATIVE PRACTICE OF MEDICINE BASED ON NON-MEDICAL GROUNDS

After *Gonzales v. Carhart*, several members of the medical community expressed concern about the decision's possible effect on the practice of medicine as a whole.[235] In particular, the concern was that Congress was dictating what was, and what was not, appropriate treatment without taking into consideration the best interests of a specific patient.[236] It is undeniable that Congress has a right to

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[230] *Id.* at 1646-47 (Ginsburg, J., dissenting).

[231] *See id.* at 1644. For example, the district courts found the doctors, who testified that the banned procedure was never medically necessary for health, had no training or experience with the procedure. *Id.* at 1646.

[232] *Id.* at 1645.

[233] *Gonzales*, 127 S. Ct. at 1646 (Ginsburg, J., dissenting).

[234] *Id.* at 1649. "The very purpose of a health *exception* is to protect women in *exceptional* cases." *Id.* at 1651.

[235] *See, e.g.*, Jeffrey M. Drazen, *Government in Medicine*, 356 NEW ENG. J. MED. 2195, 2195 (2007).

[236] *Id.*

regulate some aspects of medicine, but Congress should not have the power to directly control a patient's ability to choose a safe and effective treatment.[237]

Without recognition of a fundamental right, a congressional ban on therapeutic cloning may inappropriately constrain a patient's ability to receive appropriate treatments as recommended by her physician in order to preserve her life or health. This is not a mere hypothetical; Congress has made frequent attempts to ban both reproductive and therapeutic cloning on moral and political grounds.[238] The bills have not passed to date because one side wants a complete ban on all cloning, while the other side wants to maintain the availability of therapeutic cloning.[239] Recent scientific developments[240] may rally proponents of a comprehensive ban to act sooner than later.[241] However, if Congress does enact a flat ban, would a court sustain the ban once therapeutic cloning was proven safe and effective? If Congress prohibits a patient from submitting to safe and effective therapeutic cloning treatments to preserve his life or health, it may be impermissibly interfering with the fundamental rights to liberty and life, especially when that legislation is based on non-medical grounds.

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[237] *See* Brief for the Cato Inst. as Amicus Curiae Supporting Respondents, Gonzales v. Carhart, 127 S. Ct. 1610 (Aug. 10, 2006) (No. 05-380). *See also* Linder v. United States, 268 U.S. 5 (1925).

[238] *See* MACINTOSH, *supra* note 68, at 76-78.

[239] *Id.* at 79.

[240] *Breakthrough in Primate Cloning*, BBC NEWS, Nov. 14, 2007, http://news.bbc.co.uk/2/hi/science/nature/7094215.stm.

[241] *See generally* Arthur Caplan, *Monkey Cloning a Reason to Pause, Not Panic*, MSNBC, Nov. 13, 2007, http://www.msnbc.msn.com/id/21755931 (discussing news of the first successful cloning of monkey embryos).

## III. CAN COURTS FIND A FUNDAMENTAL RIGHT TO SAFE AND EFFECTIVE MEDICAL TREATMENTS IN THE DUE PROCESS CLAUSE?

It is true that most federal courts have declined to hold that a person has "a constitutional right to obtain" particular medical treatments that "the government has reasonably prohibited."[242] Most of these cases, however, have involved licensure issues,[243] positive rights,[244] and the use of controlled substances or other regulated drugs.[245] Although *Abigail Alliance II* and *Gonzales v. Carhart* did not find a fundamental right for the particular modalities involved in those cases,[246] the courts in both cases did not rule out future challenges asserting a fundamental right to medical treatment.[247] A court can analyze the fundamental right to safe and effective treatments in order to preserve one's life or health as recommended by one's physician under several theories. Finding support for this right is critical in order to ensure that any congressional ban on therapeutic cloning is narrowly tailored to serve a compelling interest.

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[242] Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993).

[243] *Id.* at 773 (articulating licensing requirements for acupuncturists).

[244] *See, e.g.*, N.Y. State Ophthalmological Soc'y., 854 F.2d at 1381 (concerning approval requirements for Medicare billing of assistant cataract surgeons).

[245] *See, e.g.*, United States v. Singh, 390 F.3d 168 (2d Cir. 2004) (concerning illegal distribution of controlled substances by a physician).

[246] *See* discussion *supra* Part II.E.

[247] *See Abigail Alliance II*, 495 F.3d at 701 (noting that it was not addressing "whether access to medicine might ever implicate fundamental rights"); *Gonzales*, 127 S. Ct. at 1639 (holding that the act banning the procedure was open to an as-applied challenge).

### A. There is Support for the Right Using "Liberty" and *Glucksberg*

The first consideration is whether *Glucksberg's* two-prong test supports the right to use safe and effective treatments in order to preserve one's life or health as a fundamental liberty interest.[248] This test does not apply to generalities, but a carefully-defined right might withstand judicial scrutiny if properly supported by historical evidence.[249] The right of a patient to submit to safe and effective treatments to preserve his life or health as recommended by his physician's reasonable medical judgment is both narrow and grounded in the tradition of the practice of medicine.

#### 1. *A Narrow Description of the Right*

The right, as described above, arguably meets the first prong of the *Glucksberg* test because it is narrow and carefully described. It only applies to the use of safe and effective medical treatments, rather than to any and all treatments that do not have any basis in science or medicine. This definition is not too broad because it does not include *all* medical decisions, but rather only the decision of a patient to submit to a medically-approved treatment to preserve his life or health.[250]

The definition also avoids problems that have plagued other attempts to find fundamental rights for medical decisions. It does not

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[248] *Glucksberg*, 521 U.S. at 720-21.

[249] *Id.* at 722. *See also* discussion *supra* Part II.D.1.

[250] *But see* N.Y. State Ophthalmological Soc'y., 854 F.2d at 1389 ("We disagree that the constitutional right to privacy comprehensively protects all choices made by patients and their physicians . . . .").

ask to protect the decision to use experimental modalities that "have not been proven safe and effective."[251] It does not involve the right to use a controlled substance in a manner not allowed by other federal laws.[252] It does not involve the right to use a modality that has little traditional medical support.[253] It also is a positive right; it does not require the government to provide treatment, but only that the government not interfere with treatment.[254] Therefore, this definition is not overbroad and seeks to protect only the right of a patient to submit to a safe and effective (and therefore medically-accepted) treatment, as recommended by her physician's reasonable judgment, to preserve her life or health.

It is possible that a court may still attempt to redefine this right even more narrowly to address the specific modality involved.[255] Courts may do this in an attempt to discipline its own discretion and not needlessly recognize new fundamental rights.[256] However, by adding additional criteria, a court can make it more difficult to show that history and tradition support the right.[257] In fact, a court may simply be trying to redirect the inquiry to avoid addressing a limited history of governmental restraint of a particular

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[251] *See, e.g.*, *Abigail Alliance II*, 495 F.3d at 697 (access to experimental drugs).

[252] *Contra, e.g.*, *Raich*, 500 F.3d at 866 (medical marijuana).

[253] *Contra, e.g.*, *Glucksberg*, 521 U.S. at 728 (physician-assisted suicide).

[254] *Contra, e.g.*, Harris v. McRae, 448 U.S. 297, 316 (1980) (public funding for abortions).

[255] Even when a challenger defines the proposed right carefully, courts have still sometimes decided to redefine the right. *See, e.g.*, *Abigail Alliance II*, 495 F.3d at 702; *Raich*, 500 F.3d at 866.

[256] *See* Sunstein, *supra* note 127, at 989.

[257] *Id.* at 991.

right.[258] This redefinition problem is acute in regards to therapeutic cloning. A court could choose to narrow further the right involved in a challenge to a therapeutic cloning ban to "a right to safe and effective therapeutic cloning" rather than "a right to safe and effective medical treatments." A history-based analysis would fail using such a specific definition unless the challenger could demonstrate that medical acceptance of the modality alone was evidence of historical support for therapeutic cloning.[259]

Even with the broader definition, therapeutic cloning presents a unique situation because this modality does not yet exist. Although the court did not find a right to use experimental drugs in *Abigail Alliance II*, it did not extend that holding to negate a right to those drugs once they are deemed safe and effective.[260] The flat cloning bans that have passed the United States House of Representatives in recent years, however, would prohibit any research involving human cloning.[261] Such a ban, if enacted, would prevent scientists in the United States from developing data that may one day show that therapeutic cloning is safe and effective. Without this data, and consequent FDA approval, a fundamental right to safe and effective medical treatments would not protect access to therapeutic cloning. Yet other countries without such bans, such as the United Kingdom and Singapore, will continue to make progress on the science.[262] Once scientists overcome the current technical obstacles to

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[258] *Abigail Alliance II*, 495 F.3d at 723 (Rogers, J., dissenting).
[259] Korobkin, *supra* note 39, at 184.
[260] *Abigail Alliance II*, 495 F.3d at 711.
[261] *See* MACINTOSH, *supra* note 68, at 76-80.
[262] Robertson, *supra* note 1, at 3-4.

therapeutic cloning, these nations will utilize the treatment and develop the clinical trial data necessary to show it is safe and effective.[263] Companies can utilize this foreign data to support a New Drug Application ("NDA") in the United States.[264]

Whether the FDA would approve a properly-supported NDA for a safe and effective therapeutic cloning treatment in the face of a flat cloning ban is an open question given the agency's increased politicization.[265] The FDA "shall" approve a NDA if the application meets a set of requirements, including clinical testing, that proves there is "substantial evidence" of the drug's efficacy.[266] Furthermore, an applicant has the right to a hearing during this process.[267] If the application is denied, the applicant can challenge the decision in a United States court of appeals, and the court will review the FDA's decision under the substantial evidence standard.[268] However, applicants rarely take this step, and even if an applicant did, the

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[263] *See* Korobkin, *supra* note 39, at 175.

[264] *See* 21 C.F.R. §§ 312.120, 314.106 (2008). Furthermore, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") is a collaborative effort between regulatory bodies in the United States, Japan, and the European Union to increase the efficiency of development and registration of safe and effective medicines, including the prevention of unnecessary duplication of human clinical trials. *See* ICH Frequently Asked Questions, http://www.ich.org/cache/compo/276-254-1.html (last visited Aug. 12, 2008).

[265] *See* Robertson, *supra* note 1, at 18. An example of FDA politicization of a medical decision came in 2005 when the FDA refused to approve over-the-counter sales of an emergency contraceptive for non-medical reasons. *Id.* at 18-19.

[266] 21 U.S.C.A. § 355(d) (West 2008). Substantial evidence in this context means "evidence consisting of adequate and well-controlled investigations . . . by experts qualified by scientific training and experience to evaluate the effectiveness . . . on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports . . . to have." 21 U.S.C.A. § 355(d).

[267] 21 U.S.C.A. § 355(d).

[268] 21 U.S.C.A. § 355(h). Substantial evidence here refers to the standard of review as described in the Administrative Procedures Act, not the definition that appears in the Federal Food, Drug and Cosmetic Act. *See supra* text accompanying notes 114-15.

reviewing court is unlikely to question the FDA's scientific conclusions.[269] If a ban against therapeutic cloning fell under a fundamental right, the court would instead review the applicant's constitutional challenge with a more probing examination.[270] However, even with appropriate clinical data, it is unknown whether an applicant would pay the substantial application fees for the purpose of triggering a constitutional challenge.[271]

### 2. *History and Tradition Support the Right*

The right to submit to a safe and effective treatment to preserve one's life or health is also grounded in history and tradition. First, there is little history supporting the notion that Congress has the power to ban a safe and effective medical treatment.[272] Second, concepts of "ordered liberty" include a patient's reasonable expectation that the government will not prevent her from using safe and effective treatments that her doctor recommends to preserve her health or life.[273] As a result, allowing Congress to dictate medical treatments without consideration of individual patient circumstances has the potential to sacrifice both liberty and justice.[274]

Although the Court in *Gonzales v. Carhart* stated that

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[269] Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 334-35 (2006).

[270] *See supra* text accompanying notes 116-17.

[271] The fee rate for NDAs requiring clinical data for fiscal year 2008 is $1,178,000. Prescription Drug User Fee Rates for Fiscal Year 2008, 72 Fed. Reg. 58103, 58105 (Oct. 12, 2007).

[272] *See Linder*, 268 U.S. at 18.

[273] *See* Leslie Pickering Francis, *Consumer Expectations and Access to Health Care*, 140 U. PA. L. REV. 1881, 1884-91 (1992).

[274] *See Glucksberg*, 521 U.S. at 721 (discussing that the right must be rooted in the "conscience of our people" (quoting Snyder v. Massachusetts, 291 U.S. 97, 105 (1934))).

Congress had the authority to regulate medical practice, it did not identify any prior cases where Congress actually banned an entire medical procedure.[275] Two historical cases the Court cited for support were *Jacobson v. Massachusetts*[276] and *Lambert v. Yellowley*,[277] both cases from the early part of the twentieth century. However, neither case truly supports the idea that the federal government has the power to interfere with a patient's access to a safe and effective treatment as recommended by her physician's reasonable judgment, regardless of the effect on her health.

In *Jacobson*, the Court declined to find a state statute requiring mandatory vaccinations for adults, when public health officials deemed it necessary, was unconstitutional.[278] The challenger was an adult who refused a smallpox vaccination although he was fit for vaccination.[279] Although much of the case discussed how the state legislature had the authority to choose between conflicting medical opinions regarding the safety of vaccinations generally, the Court was clear that it was not holding there was an "absolute rule that an adult must be vaccinated if . . . that vaccination . . . would seriously impair his health, or probably cause his death."[280]

In *Lambert*, the Court also declined to find a federal statute unconstitutional limiting the amount of "spirituous liquor" a

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[275] Annas, *supra* note 23, at 2205.
[276] 197 U.S. 11 (1905).
[277] 272 U.S. 581 (1926).
[278] *See Jacobson*, 197 U.S. at 39.
[279] *Id.*
[280] *Id.* at 30-31, 39.

physician could prescribe.[281] As in *Jacobson*, the Court discussed conflicting views of the medicinal purposes of spirituous liquors.[282] Even so, the reason for the case was to challenge whether Congress had the power to pass such a law in furtherance of the Eighteenth Amendment.[283] In addition, the focus was on whether a physician could prescribe amounts beyond the limits of the law, rather than whether or not a patient had a right to receive greater amounts.[284] Therefore, these cases do not support the idea that Congress has the power to prohibit a patient from submitting to a safe and effective medical treatment.

A history of respect for the concepts of bodily integrity and self-determination further support a right to access safe and effective medical treatments without unwarranted governmental interference.[285] These are not "abstract concepts of personal autonomy," but rather specific rights that one can apply to acts to preserve one's life or health.[286] Bodily integrity centers on the concept that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."[287] The

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[281] *Lambert*, 272 U.S. at 594-95.

[282] *Id.* at 589-90.

[283] *Id.* at 589. The Eighteenth Amendment prohibited the "manufacture, sale, or transportation of intoxicating liquors . . . for beverage purposes. . . ." U.S. CONST. amend. XVIII, § 1 (repealed 1933).

[284] *Lambert*, 272 U.S. at 596. The law was really intended to make sure that physicians were not overprescribing alcohol as a pretext for making it available for beverage purposes. *Id.* at 597.

[285] *See* WILLIAM BLACKSTONE, 1 COMMENTARIES *129 (discussing the guarantee to preserve one's health).

[286] *See Abigail Alliance II*, 495 F.3d at 716 (Rogers, J., dissenting) (citations omitted).

[287] Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (finding that a doctor's operation without the patient's informed consent amounted to trespass).

government has an interest in preserving the health of its citizens,[288] and not all bodily acts that a person may wish to engage in are constitutionally protected.[289] However, there are limits on the government's ability to interfere with "a person's most basic decisions about . . . bodily integrity."[290]

If history supports the right of an adult to *refuse* safe and effective treatments without governmental interference—even when that treatment would preserve his life or health[291]—then that same history also arguably supports the right of an adult to *submit* to safe and effective treatments to preserve his life or health without undue governmental interference.[292] The majority in *Abigail Alliance II* rejected a similar argument, noting that "a tradition protecting individual *freedom* from life-saving, but forced, medical treatment does not evidence a constitutional tradition of providing affirmative *access* to a potentially harmful, and even fatal, commercial good."[293] However, this conclusion ignores the fact that the Supreme Court has indicated support for bodily integrity arguments in situations where the goal was not to preserve life or health. For example, in *Glucksberg*, a majority of justices noted that their support assumed that availability of palliative treatment might implicate liberty rights even if it hastened death.[294] The *Abigail Alliance II* majority's overriding concern about potentially harmful drugs is also not at issue

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288 *See Cruzan*, 497 U.S. at 271.
289 *See, e.g., Raich*, 500 F.3d at 850.
290 *Planned Parenthood*, 505 U.S. at 849 (internal citations omitted).
291 *Cruzan*, 497 U.S. at 270.
292 *See* Goldberg, *supra* note 70, at 310.
293 *Abigail Alliance II*, 495 F.3d at 711 n.19.
294 Robertson, *supra* note 1, at 10.

when the drug has been independently deemed safe and effective.

It is impossible to consider how a court might apply history to a therapeutic cloning ban without returning to the discussion of definition.[295] If the court defines the right to include the specific treatment, the government could argue that Congress' interest in banning human cloning in recent years is a sign that history did not support a right to this particular modality.[296] However, since therapeutic cloning does not yet exist, a flat ban is not based on any evidence that the treatment will forever be unsafe or ineffective. Even once therapeutic cloning is deemed safe and effective, there will not be much "history" supporting such a novel treatment. If it is not a requirement that a statute or common law specifically recognize a fundamental right, then neither should courts require historical evidence supporting a right to access safe and effective therapeutic cloning in *Abigail Alliance II*.[297]

### B. Alternative Theories Independently Support the Right

Since the application of the *Glucksberg* test is highly dependent on the court's definition of the asserted right, a challenger may need to demonstrate the right exists using alternative theories.[298] A challenger might argue that a tradition of confidentiality in the

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[295] *See supra* Part IV.A.1.

[296] *See, e.g.*, H.R. 2564, 110th Cong. (2007); H.R. 1357, 109th Cong. (2005); H.R. 534, 108th Cong. (2003); H.R. 2505, 107th Cong. (2001). A similar argument appeared in *Raich*, where the court found that the country "took an about-face" in regards to a history of medical marijuana use when Congress passed the Controlled Substance Act in 1970. *Raich*, 500 F.3d at 865.

[297] *Abigail Alliance II*, 495 F.3d at 722-23 (Rogers, J., dissenting).

[298] *See Raich*, 500 F.3d at 864.

physician-patient relationship supports a right to safe and effective medical treatments just as those privacy rights already recognized by the Court.[299] The Hippocratic Oath, traditionally taken by physicians, includes a provision regarding the physician's duty to respect her patient's privacy.[300] Modern laws regarding exclusion of evidence of physician-patient conversations[301] and protection of medical records[302] indicate that society places great weight on the privacy of an individual's medical decisions. The *Lawrence* framework might, therefore, apply because an "emerging awareness" exists in modern times that use of safe and effective medical treatments, even those that are completely novel, such as therapeutic cloning, is a fundamental right.[303] However, this argument would not likely overcome the Court's limitation of medical privacy to procreation and contraception contexts.[304]

The right to use safe and effective medical treatments is also grounded in the textual due process right to life. The plain language of the clause enumerates this right.[305] The Court has also recognized "that the Due Process Clause protects an interest in life."[306] When an

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[299] *See Lawrence*, 539 U.S. at 582.

[300] *See* TABERS CYCLOPEDIC MEDICAL DICTIONARY 991-92 (19th ed. 2001). The Hippocratic Oath states in pertinent part: "Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret." *Id.* at 992.

[301] *See, e.g.*, CAL. EVID. CODE § 994 (West 2008).

[302] *See, e.g.*, Public Health and Welfare Law, 42 U.S.C. § 1320d-6 (b) (2000) (providing penalties for wrongful disclosure of individually identifiable health information).

[303] *See Lawrence*, 539 U.S. at 572.

[304] *See supra* text accompanying notes 156-59.

[305] U.S. CONST. amend. V.

[306] *Abigail Alliance II*, 495 F.3d at 727-28 (Rogers, J., dissenting) (quoting *Cruzan*, 497 U.S. at 281).

internal condition threatens one's life or health, that person needs external forces to intervene in order to restore health.[307] Safe and effective medical treatments have, by definition, been proven to help a person preserve her life or health. Even therapeutic cloning "involve[s] efforts to avoid death and reduce suffering."[308] It would therefore be illogical for the government to be free to legislate in a manner that threatened a person's life without a compelling interest.[309] A court should not abdicate its judicial responsibility by denying the importance of this express constitutional interest in life.[310]

The common law doctrine of self-defense lends further weight to why government restrictions to safe and effective medical treatments may infringe the fundamental right to life. The right of a person to take reasonable steps to preserve her life in the face of death has been described as "an inherent right of man."[311] The concept appears most often in regards to assaults by other people, but its basic premise also applies when one's aggressor is instead a disease.[312] When a person's life or health is seriously threatened by a disease, she should have the opportunity to fight against that disease in a reasonable manner. If her physician recommends that a particular medically-accepted treatment is her best opportunity to recover from that disease, she should have the right to submit to that

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[307] Korobkin, *supra* note 39, at 182.
[308] Robertson, *supra* note 1, at 13.
[309] *See id.* at 12.
[310] *Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).
[311] *Id.* at 717 (quoting People v. Pignatoro, 136 N.Y.S. 155, 160 (Magis. Ct. 1911)).
[312] *Id.* at 717-18.

treatment as an act of self-defense.[313] Although the right to self-defense is not unqualified,[314] courts should subject government restrictions that impose a substantial burden on the ability to protect one's life through the use of safe and effective medical treatments to a higher level of scrutiny.[315]

The concept of self-defense in the medical context is not novel. For example, post-viability abortions allowed for life and health reasons are not grounded in personal choice, but rather in self-defense.[316] In *Roe v. Wade*,[317] the Court held that states could "proscribe abortion [after fetal viability] . . . except when it is necessary to preserve the life or health of the mother."[318] The Court reaffirmed this holding in both *Planned Parenthood of Southeastern Pennsylvania v. Casey* and *Stenberg v. Carhart*.[319] Even the Court in *Gonzales v. Carhart* continued to recognize the government could not proscribe specific abortion procedures if doing so posed a significant risk to a woman's health.[320] The Court's jurisprudence in this area repeatedly emphasizes that the right to an abortion is not only based on choice. When an abortion is necessary to preserve one's life or health, clearly that abortion is sought instead as an act of self-defense.[321]

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313 *See id.* at 721.
314 *Id.* at 717.
315 *See* Volokh, *supra* note 164, at 1827.
316 *Id.* at 1826.
317 410 U.S. 113 (1973).
318 *Id.* at 163-65.
319 *See Planned Parenthood*, 505 U.S. at 846; *Stenberg*, 530 U.S. at 931.
320 *Gonzales*, 127 S. Ct. at 1635.
321 Since self-defense is a common law doctrine, it is also noteworthy that states have long exempted from criminal statutes those abortions performed to save the life of the mother.

Government restrictions regarding misbranded or adulterated drugs are not inconsistent with the self-defense concept.[322] Although the majority in *Abigail Alliance II* rejected an argument of self-defense, the court's holding was premised on the drug in question being experimental.[323] The court was clear that "[u]nlike the cases in which the doctrine of self-defense might properly be invoked, this case involves risks from drugs with no proven therapeutic effect."[324] Drugs which have been proven safe and effective through proper clinical trials would have a proven therapeutic effect. Therefore, courts should consider a patient's access to safe and effective medical treatments to preserve her life and health as a cognizable act of self-defense in pursuit of her right to life.

### C. Do Practical Policy Considerations Negate Application of Strict Scrutiny?

Courts have struck down legislation interfering with life and health in the past.[325] However, any recognition of a new fundamental right may have adverse effects on existing regulatory structures. If a patient has a fundamental right to submit to a safe and effective medical treatment to preserve her life or health, then courts would subject any law or regulation enacted that interfered with this right to strict scrutiny.[326] Existing laws could face increased challenges on grounds that there was no compelling government interest or that the

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*See Abigail Alliance II*, 495 F.3d at 721 (Rogers, J., dissenting).

[322] *Id.* at 726.

[323] *Id.* at 710 (majority opinion).

[324] *Id.*

[325] Robertson, *supra* note 1, at 14.

[326] *See* discussion *supra*, Part II.C.1.

law was not narrowly tailored. There may also be concerns that the courts would not give the appropriate level of deference to legislative or agency fact-finding.[327] However, these public policy concerns are not great enough to deny recognition of this fundamental right, especially since the government would not lose all power to regulate medical treatments.[328]

First, in order for this right to apply in a particular case, it must involve a governmental interference with a patient's decision to submit to a safe and effective treatment. Legitimate laws and regulations that restrict access to modalities not yet proven safe or effective may not fall under the protection of this right.[329] The government has rarely attempted to directly interfere with the ability of patients to submit to safe or effective medical treatments.[330] As noted above, the Partial-Birth Abortion Ban Act of 2003 ("Act") was the first time Congress completely banned a medically-accepted procedure.[331] Although parties may file more suits, a court is likely to prematurely dismiss a suit in the absence of legislative or agency action interfering with access to a medically-accepted treatment. There is also no reason why recognition of this right would cause courts any greater difficulty in assessing "compelling interests" than it does in other strict scrutiny matters.[332]

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[327] *See Richmond*, 488 U.S. at 500.

[328] *See* Robertson, *supra* note 1, at 15.

[329] The petitioners in *Abigail Alliance II* did try to argue the experimental drugs were safe since they had passed the initial stage of clinical testing, but the court did not agree. *Abigail Alliance II*, 495 F.3d at 703. Furthermore, FDA decisions denying approval of a drug could be challenged. *See* 21 U.S.C.A. § 355 (h).

[330] Korobkin, *supra* note 39, at 180-81.

[331] *See supra* note 205 and accompanying text.

[332] For example, courts apply strict scrutiny for challenges to laws on equal protection or

Second, reducing the level of deference given to congressional fact-finding in the area of medical practices is a proper use of judicial oversight. In the past, courts have deferred to the medical community's authority of what is considered proper medical practice.[333] Deference to Congress may be appropriate if Congress is better equipped than the courts to arrive at the correct result.[334] Congressional fact-finding simply consists of reviewing oral and written testimony.[335] Furthermore, Congress can choose to invite experts that meet their predetermined view of the facts to testify. More so, in the "throes of politics," Congress may overlook basic values.[336] Therefore, it is likely that congressional legislation regarding medical judgment and legitimate medical purposes will reflect political goals rather than regulatory and honest public health goals.[337]

This political reality means that courts should be particularly skeptical of congressional fact-finding for controversial medical procedures. Justice Thomas, in his role as a Circuit Judge for the Court of Appeals for the D.C. Circuit, once said that "[i]f a legislature could make a statute constitutional simply by 'finding' that black is white or freedom, slavery, judicial review would be an elaborate farce."[338] In *Gonzales v. Carhart*, the constitutionality of the Act depended on whether the ban on the specific procedure would

existing fundamental rights grounds. *See* CHEMERINSKY, *supra* note 57, at 797.

[333] *See* Bloche, *supra* note 20, at 994.

[334] Brief for the Cato Inst., *supra* note 237, at 9.

[335] *Id.* at 10.

[336] Robertson, *supra* note 1, at 23.

[337] *See* Brief for the Cato Inst., *supra* note 237, at 5.

[338] Lamprecht v. F.C.C., 958 F.2d 382, 392 n.2 (D.C. Cir. 1992).

subject women to significant health risks.[339] When Congress passed the bill, it included a dubious congressional finding of fact that the procedure was never medically necessary to preserve a woman's health.[340] While the Court admitted there was medical uncertainty over this particular issue, it also found that some of Congress' other findings were "factually incorrect."[341] However, instead of critically examining whether this finding was accurate, it simply gave deference to Congress' decision, by popular vote, that the fact *did* exist.[342] As a result, the Court erroneously deferred to Congress' findings that were based on politics rather than medical science.

Even if congressional testimony regarding a particular medical practice was completely neutral, Congress does not have the context nor capacity to accurately weigh evidence gained from such testimony.[343] Congress is not an expert in the area of medical practice regulation.[344] Although Congress regularly handles diverse issues with which it does not have specific expertise, it is examining medical practices at an unusually microdetailed level.[345] For example, when Congress enacted the Clean Air Act, it required the EPA to develop air quality standards.[346] However, Congress left it up to each state to specify how the state would meet those standards,

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339 *Gonzales*, 127 S. Ct. at 1635.

340 Partial-Birth Abortion Ban Act of 2003, § 2(2), (5).

341 *Gonzales*, 127 S. Ct. at 1636-38.

342 *Id.* at 1637. *See Lamprecht*, 958 F.2d at 392 n.2 ("We know of no support . . . for the proposition that if the constitutionality of a statute depends in part on the existence of certain facts, a court may not review a legislature's judgment that the facts exist.").

343 Kassirer, *supra* note 16, at 1747.

344 *See* Brief for the Cato Inst., *supra* note 237, at 7.

345 Kassirer, *supra* note 16, at 1747.

346 42 U.S.C. § 7408(a) (2000 & Supp. IV).

recognizing that each state's situation was unique.[347] In comparison, the Act does not allow for this level of flexibility in application since it completely bans an entire procedure, regardless of individual patient circumstances. "Laws are blunt instruments that are of little value" when applied to a particular patient's medical crisis.[348] Courts should, therefore, review congressional legislation that bans safe and effective medical treatments with skepticism.

Finally, courts would likely continue to analyze constitutional claims against agency decision making as they do today. Courts, not agencies, are experts in constitutional matters.[349] As a result, courts will not give deference to agency decisions that may infringe a constitutional right.[350] However, courts generally will give agencies deference in areas that involve complex, technical expertise.[351] Courts will most likely grant deference to federal medical regulations that are promulgated under a constitutional statute. However, courts should limit administrative authority in this area when the government merely has legitimate grounds for banning "safe and effective medical treatments."[352]

## IV. A JUDICIAL DECLARATION OF A FUNDAMENTAL RIGHT TO SAFE AND EFFECTIVE MEDICAL TREATMENTS

In order to prevent unnecessary congressional interference with the medical treatment options available to patients, the Supreme

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347 42 U.S.C. § 7410(a) (2000 & Supp. IV).
348 Drazen, *supra* note 21, at 178.
349 *Califano*, 592 F.2d at 780 n.15.
350 *Id.* at 780.
351 *Id.* at 780 n.15.
352 *See* Robertson, *supra* note 1, at 16.

Court should recognize that a patient has a fundamental right to submit to safe and effective medical treatments as recommended by his physician's reasonable medical judgment to preserve his life or health. The Due Process Clause's protection of "liberty" and "life" both support this right. Therefore, the government must narrowly tailor any laws infringing on this fundamental right to meet a compelling government interest. This recognition is important not only to prevent the federal government from impermissibly interfering with a patient's ability to access current medically-accepted modalities, but also to ensure the availability of future treatments. Under this solution, courts would subject a congressional ban on therapeutic cloning to strict scrutiny once the modality was deemed safe and effective.

### A. How Would Strict Scrutiny Apply to a Ban on Therapeutic Cloning?

The right as described only applies to safe and effective medical treatments.[353] Therefore, the government could continue to regulate future treatments which have not yet been "medically accepted" with only a rational basis review, even if the Court did recognize this right as fundamental. Under rational basis review, a court would likely uphold a ban against therapeutic cloning before it was deemed safe and effective because the government could likely proffer legitimate safety interests for the ban. If Congress enacted such a ban under these circumstances, patients would not have access to therapeutic cloning treatments until they were proven safe and

[353] *See supra* Part IV.A.1.

effective. As discussed above, scientific evidence of safety and efficacy would have to come from foreign research if the United States passed a comprehensive ban.[354] However, assuming that data was available proving that therapeutic cloning was safe and effective, a party could bring a constitutional challenge against the ban.[355] As a fundamental right, courts must therefore review the ban using strict scrutiny.

### 1. *What Interests Might the Government Proffer, and are These Interests Compelling?*

There are two categories of interests the government would likely proffer as justification for a ban against therapeutic cloning.[356] The first category involves traditional governmental health and safety interests.[357] The second category involves moralistic judgments about both embryonic life and cloning in general.[358] If therapeutic cloning is safe and effective, none of these interests are compelling.

Just as with other experimental drug regulations, the government's interest in protecting public health is important.[359] The FDA performs a cost-benefit analysis when it reviews new drugs for approval; if the drug is unsafe or ineffective compared to the

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[354] *See supra* text accompanying notes 262-69. In addition, the FDA already tends to approve drugs that are approved elsewhere, which indicates the agency does utilize medical and scientific evidence generated in foreign countries. *See* Steenburg, *supra* note 269, at 324.

[355] See *supra* text accompanying notes 265-71 regarding the potential hurdles of demonstrating therapeutic cloning was safe and effective after the enactment of a flat ban.

[356] *See, e.g.*, H.R. 2564, 110th Cong. (2007).

[357] *See id.*

[358] *See id.*

[359] Korobkin, *supra* note 39, at 184.

potential benefit to the patient, the agency may deny approval.[360] However, if therapeutic cloning is deemed safe and effective, then the government's health and safety interests would cease to be compelling.[361] Furthermore, in the case of a cloning ban, it is clear that the government is not restricting access because it is truly concerned about safety and efficacy.[362]

The primary motivation behind comprehensive cloning bans is actually premised on a particular viewpoint that finds the technology involved in therapeutic cloning to be immoral.[363] The current technology utilized to harvest embryonic stem cells results in the destruction of the source embryo, regardless of whether the embryo is fertilized naturally or cloned.[364] Some members of Congress and the Executive Branch have indicated that the protection of embryos is a paramount government interest.[365] This viewpoint places great value in the potential life of the embryo.[366] Others have argued the government's real concern is a general repugnance for cloning technologies, since the "potential life" argument is generally ignored in regards to excess embryos destroyed after fertility

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[360] *Id.*

[361] *Id.* at 187.

[362] *Id.* at 184.

[363] *Id.* at 179.

[364] Korobkin, *supra* note 39, at 163.

[365] *See* 152 CONG. REC. H5216 (2005) (statement of Rep. Weldon) ("You don't need to destroy embryos. You don't have to use taxpayer dollars for the destruction of human life."); Press Release, The White House, President Discusses Stem Cell Research Policy (July 19, 2006), http://www.whitehouse.gov/news/releases/2006/07/20060719-3.html ("Yet we must also remember that embryonic stem cells come from human embryos that are destroyed for their cells. Each of these human embryos is a unique human life with inherent dignity and matchless value.").

[366] Goldberg, *supra* note 70, at 306-07.

treatments.[367] There are those who also argue that therapeutic cloning will impermissibly lead to reproductive cloning.[368] All of these arguments are based on moral viewpoints that are not shared by all people.

Although the "culture of life" is a powerful force in politics and law today,[369] it simply cannot provide a compelling interest to warrant a ban on medically-accepted treatments that benefit the existing population.[370] Assigning legal rights to an embryo merely because it has human DNA does not justify depriving existing humans of safe and effective treatments.[371] In *Lawrence*, morality alone was insufficient to meet a review that was something more than rational basis review.[372] If morality cannot meet that level of review, then it certainly cannot meet the higher compelling standard under strict scrutiny. It has been said that "one person's disgust, even with government support, should not override another's fundamental right."[373] This is particularly important when moral intuitions may indicate unfamiliarity or prejudice, as in the case of human cloning.[374] A ban on therapeutic cloning based on a desire to protect embryonic life or express repugnance toward cloning would likely not survive under a strict scrutiny standard of review.

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[367] *Id.*

[368] *See, e.g.*, H.R. 2564, 110th Cong. (2007).

[369] Robertson, *supra* note 1, at 1.

[370] Even the majority in *Gonzales* accepted that the government could not prohibit a woman from obtaining a pre-viability abortion. *Gonzales*, 127 S. Ct. at 1626.

[371] Robertson, *supra* note 1, at 23.

[372] *Lawrence*, 539 U.S. at 577.

[373] Korobkin, *supra* note 39, at 188.

[374] *Id.* at 172.

### 2. *Is a Comprehensive Ban on Therapeutic Cloning Narrowly Tailored?*

Assuming that the Court did find that safety concerns or protection of potential embryonic life were compelling government interests, the Court must consider whether the law is narrowly tailored to meet these interests. A review of one proposed ban on therapeutic cloning provides insight of what one might expect in a future law.[375] The proposal bans all performances, attempted performances, or participation in human cloning as well as the shipment, receipt, or importation of the product of human cloning "for any purpose."[376] Proper consideration of this proposal demonstrates it is not narrowly tailored to meet either of the likely proffered government interests.

In regards to safety concerns, this proposal makes no provision for use or importation of therapeutic cloning treatments once they are deemed safe and effective.[377] Restrictions may be appropriate before the treatment is medically accepted, just as with other experimental drugs. However, once the treatment is proved safe and effective using standard criteria, safety reasons no longer provide justification for a complete ban. This does not mean that patients must have unregulated access; the government could place some restrictions on use if warranted by medical facts. However, a ban that does not permit even the hope of using the treatment once safe and effective is too broad and is not narrowly tailored.

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375 *See* H.R. 2564, 110th Cong. (2007).
376 *Id.*
377 *See* Goldberg, *supra* note 70, at 306 n.3.

This law is also not narrowly tailored to support an interest in protecting embryonic life. The primary argument in this regard is that the ban is underinclusive. Under a rational basis review, it may be acceptable that this proposal does not ban all procedures, such as in vitro fertilization ("IVF"), that result in the destruction of embryos.[378] However, under strict scrutiny, failing to ban the disposition of spare embryos after IVF is suspect.[379] If therapeutic cloning is banned because it destroys embryos, then it is illogical not to also ban the destruction of embryos created through IVF procedures.

Furthermore, a flat ban is not narrowly tailored to eliminate the risk that therapeutic cloning may impermissibly lead to reproductive cloning. This is easily demonstrated by comparing the language of a flat ban with other proposed laws. A flat ban from the United States House of Representatives defines "human cloning" to mean using somatic cell nuclear transfer to create a living organism "at any stage of development."[380] This clearly includes the creation of cloned embryos for use in therapeutic cloning. In comparison, a proposed law from the United States Senate defines "human cloning" to mean only when a cloned embryo is actually implanted into a uterus.[381] This bill would prohibit reproductive cloning, but would not ban therapeutic cloning since those embryos are not implanted into a uterus. A comprehensive, flat ban including therapeutic

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[378] *See* Williamson v. Lee Optical of Okla. Inc., 348 U.S. 483, 488-89 (1955) (articulating the Court's standard for rational basis review).

[379] *See* Goldberg, *supra* note 70, at 312.

[380] H.R. 2564, 110th Cong. (2007).

[381] S. Res. 812, 110th Cong. (2007).

cloning is therefore not narrowly tailored to meet a particular moral view regarding cloning or the potentiality of embryos, nor is it narrowly tailored for safety concerns.

## V. CONCLUSION

Federal regulation of medical practice occurs at both the legislative and agency levels.[382] Current judicial practice gives a great deal of deference to these regulations in the absence of potential infringements on fundamental rights.[383]However, federal regulations that broadly restrict the availability of a medically-accepted treatment based on non-medical grounds pose a threat to the health and well-being of individual citizens. A flat ban on therapeutic cloning is an example of how such legislation could risk a patient's health well into the future. Although the Supreme Court has recognized some fundamental rights in the area of medicine,[384] it has not yet recognized a right for a patient to submit to safe and effective treatments to preserve her life or health on the recommendation of her physician's reasonable medical judgment. The courts should declare that this right is fundamental and cease to defer to political congressional fact-finding in such situations. Only then will Congress stop making unqualified, moralistic forays into the practice of medicine.

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[382] *See* Kassirer, *supra* note 16, at 1747.
[383] *See Pryor*, 240 F.3d at 948.
[384] *See Lawrence*, 539 U.S. at 574.